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510k Summary

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Proprietary Name: Scansystem™

Common Name: Bacterial detection system for the quality control testing of leukocyte reduced apheresis platelet units (LRAP)

Classification Name: MZC

Predicate Device: BacT/ALERT® 3D Microbial Detection System and BacT/ALERT® Culture Bottles

Description of the Device:

The Scansystem™ bacterial detection system is comprised of the Scansystem™ Sampling Device, the Scansystem™ Platelet Kit, the Scansystem™ Analyzer, including an epifluorescent microscope, and software to analyze results and facilitate visual confirmation of results by the operator. The Scansystem™ Sampling Device facilitates the pooling of samples from up to three LRAP units. The Scansystem™ Platelet Kit concentrates the bacteria in the LRAP pool, labels them using a fluorescent dye which is a double strand, DNA-specific marker, and deposits the residual bacteria onto a black membrane after filtering for analysis by the Scansystem™ Analyzer. The Analyzer is a solid phase cytometer which uses a laser to scan the entire membrane surface and analyzes the resulting data, differentiating between labeled bacteria and debris. The results are then transferred to a computer memory. The results are available as a scan map which shows the location of each detected bacterium. With the aid of a link to a motor-driven epifluorescent microscope stage, the operator visually confirms a random selection of fluorescent signals and the results are presented as "number of bacteria detected." The final interpretation is determined by the operator, after the ratio of confirmed positive signals to total number of fluorescent signals has been calculated and determined to be positive or negative.

Intended Use of the Device:

For *in vitro* diagnostic use; the Scansystem™ bacterial detection system is intended to be used to detect bacterial contamination in leukocyte reduced apheresis platelets (LRAP) for quality control testing. It is intended to be used by trained technicians.

Technical Characteristics:

The Scansystem™ Sampling Device is an empty sample transfer set with ports, sample pouches, breakable cannulae leading to a pooling/mixing chamber, and a port for connection to the Scansystem™ Platelet Kit. The Scansystem™ Platelet Kit contains ready-to-use reagents and chambers with breakable cannulae to allow the fluorescent labeling of bacteria, the aggregation of platelets, the permeabilization of bacteria cell membranes, and the plating of residual fluorescent bacteria in the LRAP sample onto a black filter.
The Scansystem™ Analyzer consists of an Argon Laser for scanning at 488 nm, computer with related keyboard, joy-stick module/mouse, monitor, and an epifluorescent microscope.

Substantial Equivalence to a Predicate Device:

The Scansystem™ bacterial detection system is substantially equivalent to the BacT/ALERT® 3D Microbial Detection System and BacT/ALERT® Culture Bottles for bacterial detection in LRAP units during quality control testing. The following table summarizes the technological characteristics of the Scansystem™ in comparison to those of the predicate device: